

I. The Office Action

The February 1, 2007 non-final office action (the “Office Action”) in this application:

1. objected to claim 1;
2. rejected claim 13 under 35 U.S.C. 112, second paragraph; and
3. rejected claims 1, 4, 5, 9, 12, 13, 31 and 32 under 35 U.S.C. 112, first paragraph.

Applicants respond as follows.

II. Amendment to claims 1, 12, 13 and 31 and objection to claim 1

The term “is” has been deleted from claims 1, 12 and 31, in order to correct this typographical/grammatical error. Accordingly, the objection to claim 1 is overcome and the objection should be withdrawn.

Support for toxin administration “in an amount between about 0.01 U/kg to about 35 U/kg” in amended claim 13 can be found at least at page 20, lines 19-20 of the specification.

III. Rejection of claim 13 under 35 U.S.C. 112, first paragraph

The Office Action rejected claim 13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention.

Claim 13 is rejected for lack of antecedent basis for reciting the limitation "...wherein the botulinum toxin is selected from the group consisting of botulinum toxin types A, B, C1, D, E, F and G". Accordingly, this recitation has been deleted from claim 13. Claim 13 now recites administration of toxin in the range from between about 0.01 U/kg to about 35 U/kg, support for which can be found at least at page 20, lines 19-20 of the specification.

Thus, this rejection should be withdrawn.

IV. Rejection of claims 1, 4, 5, 9, 12, 13, 31 and 32 under 35 U.S.C. 112, first paragraph

The Office Action rejects claims 1, 4, 5, 9, 12, 13, 31 and 32 under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement, alleging that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants traverse the rejection.

Applicants respectfully submit that the instant specification conveys with clarity to one skilled in the relevant art that applicants had possession of the claimed invention at the time the application was filed. In general, the pending claims are directed to a method for treating a face pain, wherein a therapeutically effective amount of botulinum toxin is administered to a region of a face pain, wherein the pain is not associated with a muscle disorder or a headache.

The instant specification clearly discloses treatment of pain, and in particular, a method for treating a face pain. For example, support for recitation of a method to treat pain which is not associated with a muscle disorder or headache is clearly provided, for example, at pages 19, line 27 to page 20, line 1 of the specification. Additionally, the specification clearly discloses that a face pain can be treated in accordance with the teachings provided therein, evidenced at least by page 43, line 7, where a face pain, as well as treatment of that face pain (which is not associated with a muscle disorder or headache) by administration of botulinum toxin is clearly disclosed (Example 4), as one of ordinary skill in the art would clearly and easily understand.

Respectfully, the Office Action has not met its burden of presenting evidence or reasoning to explain *why* persons skilled in the art would not recognize that the disclosure provides a description of a method for treating a

face pain, as defined by the claims. Instead, the Office Action asserts its written description rejection by stating that the disclosure of a single species of face pain (here, Example 4 as one example of a face pain) does not provide written description for various types of face pain (Office Action, page 3, lines 15-21). Applicants respectfully disagree.

The inquiry as to whether the pending claims comply with the written description requirement is primarily factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure. Accordingly, there is no failure of the instant claims to comply with the written description requirement simply because the specification does not list or disclose a particular and/or unstated number of types of face pain not due to a headache or associated with a muscle disorder, that the Office Action deems that the disclosure is required to recite (please see page 3 lines 14-15), so that only then is the written description requirement is fulfilled. Respectfully, such an assertion is improper, as discussed below.

A skilled artisan would have clearly understood that the inventors possessed the claimed invention at the time of filing and accordingly the written description requirement is met. For example, a skilled artisan reading the instant application, as a whole, would clearly determine that the application, as filed, discloses and describes the act of peripherally administering botulinum toxin to a face of a person in order to treat the face pain, where the pain is not associated with a muscle disorder or a headache. Treatment of a face pain cannot be more clearly expressed in the instant application than the "Pain in the face", expressly disclosed in the instant application (Example 4 page 43, line 7). As such, one of ordinary skill in the relevant art is clearly apprised and informed that a face pain is the type of pain that is disclosed and treated in this example. The teaching of treating a face pain by peripheral administration of a botulinum toxin is further, fully and clearly supported by the clear and explicit disclosure that the pain to be treated, in this exemplary treatment, is located in the lower left cheek (page 43,

lines 10-11 of the instant application), which one of ordinary skill in the art clearly understands to be part of a person's face. Accordingly, the instant claims do comply with the written description requirement, as one of ordinary skill in the art would assert based on the instant application's teaching of treatment of face pain, as discussed above.

Thus, this rejection should be withdrawn.

V. Conclusion

All issues raised in the Office Action have been addressed. Reconsideration and allowance of claims 1, 4, 5, 9, 12, 13, 31 and 32 is requested.

The Commissioner is hereby authorized to charge any fee(s) required or necessary for the filing, processing or entering of this paper or any of the enclosed papers and to refund any overpayment to deposit account 01-0885.

Respectfully submitted,

/Claude L. Nassif/

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